

REMARKS

Claims 8 to 16 Are Cancelled

The Examiner has concluded that claims 8 to 16 are patentable if rewritten in independent form.

I respectfully request the Examiner to please cancel claims 8 to 16. Applicant may in the future file a continuation application including these claims.

Claims 23 To 34 Are Amended To
Particularly Point Out The Claimed Invention

The Office Action suggests that claims 23 to 34 be amended and rearranged to include an appropriate transitional phrase.

I would like to thank the Examiner for your constructive input. I have amended the claims according to your suggestion, and hope you find the amendments satisfactory.

Patentability

The Office Action alleges that claims 1 to 7 and 17 to 40 are obvious in light of Fanie Retief VAN HEERDEN *et al.*, *Pharmaceutical Compositions Having Appetite Suppressant Activity*, U.S. Letters Patent No. 6,376,657. I respectfully disagree, because the Office Action fails to state a *prima facie* case of obviousness.

**I. THE OFFICE ACTION
FAILS TO STATE A *PRIMA*
FACIE CASE OF OBVIOUSNESS**

A *prima facie* case of obviousness requires three elements. *In re Vaeck*, 947 F.2d 488 (Fed.Cir. 1991). First, the reference must teach each element of the claims at issue. Second, the reference must teach a reasonable expectation of success. Third, the reference must suggest combining the art of record to replicate the claimed invention.

In the immediate case, the reference fails to fulfill any one of these three required elements. The OFFICE ACTION therefore fails to state a *prima facie* case.

A. The reference fails to teach every claim element

The claims require “weigh loss,” and *hoodia gordonii*, and certain administration periods.

For example, independent claim 1 reads:

1. A method of body weight reduction, comprising administering a body weight reducing amount of *hoodia gordonii* at least once every about 48 hours, for a least about 45 days.

In contrast, Independent claim 35 reads:

35. A method of body weight reduction, comprising administering *hoodia gordonii* in an amount sufficient to suppress the appetite after said administration, said administration repeated a plurality of times, each said time occurring before said *hoodia gordonii* causes an appetite stimulating effect.

In contrast, Independent claim 19 reads:

19. A composition of matter for body weight reduction, comprising a body weight reducing amount of *hoodia gordonii* together with a second compound selected from the group consisting of a stimulant and glucosamine...

The independent claims thus require weigh loss, *hoodia gordonii*, and certain administration periods.

The prior art must teach each and every element of the claims at issue. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). In the immediate case, however, the reference fails to teach each claim element of any independent claim.

The reference fails to teach weight loss. Rather, the reference teaches appetite suppression. See Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 14 to 15. Appetite suppression is not the same thing as weight loss. *Id.* at ¶¶ 9 to 13. The reference itself

says this. *Id.* Thus, while the reference teaches appetite suppression, it fails to teach weight loss. *Id.*

The reference teaches the use of 3-O-[β -D-thevetopyranosylcymaropyranosyl]-12 β -O-tigloyloxy-14 β -hydroxy-14-pregn-50-en-20-one. See Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 42 to 43. The reference does not teach nor claim a new use of the *hoodia* plant. *Id.*

The reference fails to teach the claimed novel periods of administration. See Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 44 to 46; see also OFFICE ACTION at 3.

The OFFICE ACTION fails to state a prima facie case of obviousness because the reference fails to teach each element of any pending independent claim.

B. The reference teaches a reasonable expectation of failure, not success

A *prima facie* case of obviousness requires that the prior art teach a reasonable expectation of success. *In re Sibia Neurosciences, Inc.*, slip opinion 05-1072 (Fed. Cir., Nov. 29, 2005) at page 3; *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136 (Fed. Cir. 1986). In the immediate case, the reference teaches compositions which induce weight *gain*. See Albert M. FLEISCHNER, Declaration (20 December 2005) at ¶¶ 16-36. The reference therefore teaches a reasonable expectation of not success, but *failure*. *Id.*

C. The reference fails to provide any motivation to modify the prior art to make the claimed invention

A *prima facie* case of obviousness requires identification in the prior art of record of some suggestion to modify the prior art to reach the claimed invention. *In re Lee*, 277 F.3d 1338, 1344 (Fed.Cir., 2002) (there must be some “hint or suggestion in a particular reference”).

In the immediate case, the OFFICE ACTION fails to identify in the art of record any suggestion to modify the prior art.

Furthermore, there can be no motivation to modify a reference where the reference itself teaches that the modification would not work. *See Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353, 1360 (Fed.Cir. 1999). In the immediate case, the reference teaches that the claimed combination would not work. *See* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 17 to 41. Thus, the art of record fails to provide a motivation to make the claimed modification.

II. THE CLAIMED INVENTION SHOWS SECONDARY INDICIA OF NON-OBVIOUSNESS

The claimed invention has several secondary indicia of non-obviousness. These include unexpectedly successful results, achieving a new and different function, and widespread copying by competitors.

A. The Inventor has achieved unexpected success

Contrary to the teachings of VAN HEERDEN, the inventor has shown that *Hoodia gordonii* is effective for weight loss. *See* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 47 to 56 and Exhibits. His results would not have been expected by one of skill in the art at the time the inventor made his invention. *Id.* at ¶ 57. There is a nexus between the inventor's scientific results and the pending patent claims, because these results would be considered by one of skill in the art to have probative value in showing the pending patent claims are enabled and are non-obvious. *Id.* at ¶ 58 to 59.

B. The inventor has achieved a
new or different function

While not required for non-obviousness, achieving a new or different function indicates the claimed invention is non-obvious. *See Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, rehearing denied, 426 U.S. 955 (1976); *Anderson's Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969). In the immediate case, the inventor has achieved a function which is not only different from the prior art, but the opposite of it. While the prior art of record teaches methods to *increase* body mass, the inventor claims methods to *decrease* body mass. This indicates the claimed invention is non-obvious.

C. The claimed invention is being widely copied

The claimed invention is being widely copied. I have previously made of record evidence of such copying. *See* PETITION TO MAKE EXAMINATION SPECIAL PURSUANT TO M.P.E.P. SECTION 708.02 (II) (6 July 2005). I respectfully believe this evidence indicates the claimed invention is non-obvious.

**III. THE SPECIFICATION
MIGHT WANT TO BE AMENDED**

Dr. FLEISCHNER's DECLARATION notes a misstatement in the Specification. As filed with the Patent Office, the Specification at page 3, lines 5 *et seq.*, says:

Hoodia gordonii is a cactus. It has been used for years by the San tribesmen in South Africa to temporarily prevent hunger during extended hunting expeditions, during which food might not have been readily available. This use occurred as early as 1937, when a Dutch anthropologist studying the San noted their use of the *Hoodia* cactus.

Since the date that this patent application was filed, the Inventor has learned that this statement is not correct. To the contrary, Dr. Marthinus HORAK, a scientist at South Africa's Council for Scientific and Industrial Research, says that "the oft-quoted story that the San ate Hoodia to stave

off hunger is 'nonsense'." See Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶ 60. Rather, the Inventor notes that Dr. HORAK says that the San "do occasionally consume [*hoodia*] for its water content." *Id.*

Thus, it appears that the San did in fact consume *hoodia*, albeit for its water content rather than for appetite suppression. I believe that this issue is not particularly germane to the patentability of the immediate claims. If, however, the Examiner would prefer that I amend the Specification to correct this statement, I will do so; simply let me know your preference in the next OFFICE ACTION.

IV. CONCLUSION

I trust that the Inventor's DECLARATION and my own remarks have adequately addressed the issues raised in the OFFICE ACTION. I thus respectfully think that the claims are in condition for prompt allowance.

Respectfully Submitted,
PHARMACEUTICAL PATENT ATTORNEYS, LLC

/s/

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IN THE DRAWINGS

No amendment.